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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,151	10/27/2003	Stephen C. Porter	03-116 (US01)	6462

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EXAMINER	
HOUSTON, ELIZABETH	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,151	PORTER, STEPHEN C.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,32-38 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,32-38 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on 11/02/06. These drawings are acceptable.

Claim Objections

2. Claims 27 and 38 are objected to because of the following informalities: Claims 27 and 38 are both dependent from claim 1 and recite the same limitations. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-30, 32-38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "an active element having a pre-deployed configuration carried *entirely* within the lumen, *no portion* of the pre-deployed active element is located outside of the lumen does not have support in the specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1, 2, 4-7, 10, 12, 14-17, 19, 20, 30, 32-34 and 40 rejected under 35 U.S.C. 102(e) as being anticipated by Ferrera et al. (USPN 6,616,617).**

7. Ferrera discloses vaso-occlusive device comprising an elongate occlusive member defining a longitudinal axis (for example Fig. 1) having an elongate axial lumen (for example opening for 14) and an active element (48, Fig. 10) having a pre-deployment configuration carried entirely within the lumen. Regarding claims 30 and 32, the vaso-occlusive device comprises a coil (Fig. 3) having a lumen (for example opening for 14). No portion of the pre-deployed active element is located outside of the lumen. The active element is configured to expand or contract to a deployed configuration when placed in the body to cause the occlusive member to retain its shape. The active element when it is shape memory inherently expands and contracts or compresses and elongates as it is twists and bends into the deployed configuration

(for example Fig. 8). The active element helps the occlusive member to retain its shape because it is the active element that induces or creates the secondary or tertiary shape (for example when the active element is a shape memory material). The active element when it is hydrogel will inherently expand or contract as a result of the properties of the hydrogel absorbing fluids and releasing therapeutic agents. The expansion of the internal strand will inherently cause the occlusive member to retain shape. The active element is secured to the occlusive member at one or both ends and at one or more locations along the length of the occlusive member. The active element is a hydrogel comprising collagen or lactic/glycolic acids, a shape memory alloy or a shape memory polymer (Col 6, lines 25-35 and Col 13, lines 40-51). The active element when in the body may be expanded to have a cross sectional dimension that is at least 100% of the internal diameter of the occlusive member (since the initial cross section dimension of the active member is already 100% of the internal diameter of the occlusive member before it enters the body and since it is inherent that the active member will expand, then it is inherent that it will expand to at least 100% of the internal diameter).

8. **Claims 1-5, 14-16, 19, 20, 24, 28, 29, 32, 33, 36 and 40 rejected under 35 U.S.C. 102(e) as being anticipated by Ken et al. (USPN 6,193,728).**

9. ~~Ferrera~~ KEN discloses vaso-occlusive device comprising an elongate occlusive member (102, 202), which is a coil defining a longitudinal axis having an elongate axial lumen and an active element (108, 214) having a pre-deployment configuration carried entirely within the lumen. No portion of the pre-deployed active element is located

outside of the lumen. The active element or stretch resisting member, such as the coil 214 in figure 1c, will stretch and expand its length longitudinally while at the same time contract its diameter while causing the occlusive member to substantially retain its shape when deployed. In the same respect, the stretch resisting member (133) in figure 3c, is loose when the coil (135) is not stretched or non-deployed and then expands by stretching to resist axial stretching of the coil when it is deployed in its maximum stretched condition (Col 8, lines 1-11). The active element is secured to the occlusive member by an adhesive at one or both ends and at one or more locations along the length of the occlusive member (Col 5, lines 1-3). The active element has an elongate shape (Fig 1A) and a coil shape (Fig. 1C). The active element comprises shape memory alloy or a shape memory polymer (Col 5, line 31 and Col 6, line 46-48). The active element can be a fiber comprising protein (Col 6, line 64).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **Claims 6, 7, 10, 12, 30, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken in view of Ferrera.**

12. Ken discloses the occlusive device with active element as stated above. Ken states that the active element may comprise a bundle of threads or a single filament

(Col 4, line 45). Ken also states that it is desirable to incorporate one or more strands to provide stiffness or electrical conductance (Col 4, line 58). Ken does not disclose that the active element comprises a hydrogel.

13. Ferrera discloses a vaso occlusive device made of multi-stranded micro-cable. The multi-stranded cable has several embodiments, which incorporate the use of shape memory material or hydrogels for drug delivery. The active element is a hydrogel comprising collagen or lactic/glycolic acids, a shape memory alloy or a shape memory polymer (Col 6, lines 25-35 and Col 13, lines 40-51).

14. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of a multistranded microcable containing hydrogel into the active element in the occlusive device since it will enhance the device by providing timed release drug delivery to the body at the site of treatment. Both Ferrera and Ken offer motivation. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

15. **Claims 7-9, 11, 13, 18, 21-29, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera in view of Sawhney (US Pub 2001/0046518).**

16. **Claims 8, 9, 11, 13, 21-29, 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken in view of Ferrera as applied to claims 6, 7, 10, 12, and 34 above and further in view of Sawhney (US Pub 2001/0046518).**

17. Ferrera and Ken in view of Ferrera disclose the invention substantially as claimed as stated above except for the material that makes up the hydrogel.

18. Sawhney discloses a hydrogel used for delivery of therapeutic agents. The hydrogel comprises polypropylene glycol or poly-hydroxyalkyl methacrylate (Para 37,38). The hydrogel comprises polysaccharides, hyaluronic acid or heparin (Para 35). The hydrogel further comprises chemical cross-linking agents (Para 31). The hydrogel is thermoresponsive (Para 40). The hydrogel comprises a polyelectrolyte (Para 38) and undergoes an ionic concentration induced shape change (Para 40). The active element can be a fiber (Para 37 and 62), which undergo a thermally induced phase change or a pH induced phase change (Para 40). The active element expands within about 10-20 minutes of being placed in a body and will increase to between 110 and 200 percent of the internal diameter of the coil (Para 28).

19. As to claims 27 and 38, when the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, *the hydrogel is comprised of a polyelectrolyte*) except for a property or function (in the present case, *the solvent will diffuse out of the gel upon contact with the blood causing the active element to contract*) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a

basis for shifting the burden of proof to applicant, as per In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the materials disclosed by Sawhney into the hydrogel of Sepetka and Jones. Sawhney provides the motivation in that the hydrogel disclosed provides advantages over prior art hydrogels. For example, they undergo a relatively large degree of swelling and hydrate relatively quickly with out degradation of mechanical properties (Para 23, 25).

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
11/4/06